NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. et al.,	
Plaintiffs,	Civil Action No. 08-5103 (SRC)
v.	**OPINION**
WATSON LABORATORIES, INC. et al.	
Defendants.	

CHESLER, U.S.D.J.

This matter comes before the Court on three motions: 1) the motion for partial summary judgment regarding utility and enablement by Plaintiff Ortho-McNeil-Janssen Pharmacueticals, Inc. ("Ortho"); 2) the motion for partial summary judgment of invalidity for double patenting by Defendant Watson Laboratories, Inc. ("Watson"); and 3) the motion for partial summary judgment of invalidity for double patenting by Defendant Lupin Pharmaceuticals, Inc. ("Lupin.") For the reasons stated below, Plaintiff's motion will be granted and Defendants' two motions will be denied.

BACKGROUND

This is a patent infringement case brought under the Hatch-Waxman Act. On April 10, 2001, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 6,214,815 (the "'815 patent"). Ortho owns the '815 patent. The claims of the '815 patent cover the combination oral contraceptive that Ortho markets under the name "Ortho Tri-Cyclen Lo."

In July of 2003, Watson filed an Abbreviated New Drug Application ("ANDA"), No. 90-479, with the United States Food and Drug Administration, seeking approval to market a generic version of Ortho Tri-Cyclen Lo prior to the expiration of the '815 patent. On September 4, 2008, Watson notified Ortho of its certification that the '815 patent is invalid due to anticipation, obviousness, and other grounds. On October 16, 2008, Ortho initiated the instant action by filing a Complaint for infringement of the '815 patent. Lupin has filed a similar ANDA, and Ortho filed a separate action against Lupin, which was consolidated into this action.

The present motions concern claims 1 and 4 of the '815 patent. Among its affirmative defenses to Ortho's claims of patent infringement, Watson contends that claims 1 and 4 are invalid on the following grounds: 1) failure to meet the statutory utility requirement; 2) failure to meet the statutory enablement requirement; and 3) nonstatutory double patenting, in view of U.S. Patent No. 4,616,006 (the "'006 patent"). Ortho has moved for partial summary judgment as to Watson's affirmative defenses of invalidity based on the utility and enablement requirements, and Watson has moved for partial summary judgment as to its affirmative defense of invalidity based on nonstatutory double patenting. Lupin has moved for partial summary judgment as to the double patenting issue, relying on Watson's briefing.

ANALYSIS

I. Relevant legal standard

A. Motions for summary judgment

Summary judgment is appropriate under FED. R. CIV. P. 56(c) when the moving party demonstrates that there is no genuine issue of material fact and the evidence establishes the moving party's entitlement to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S.

317, 322-23 (1986). A factual dispute is genuine if a reasonable jury could return a verdict for the non-movant, and it is material if, under the substantive law, it would affect the outcome of the suit. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). "In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the non-moving party's evidence 'is to be believed and all justifiable inferences are to be drawn in his favor.'" Marino v. Indus. Crating Co., 358 F.3d 241, 247 (3d Cir. 2004) (quoting Anderson, 477 U.S. at 255).

"When the moving party has the burden of proof at trial, that party must show affirmatively the absence of a genuine issue of material fact: it must show that, on all the essential elements of its case on which it bears the burden of proof at trial, no reasonable jury could find for the non-moving party." In re Bressman, 327 F.3d 229, 238 (3d Cir. 2003) (quoting United States v. Four Parcels of Real Property, 941 F.2d 1428, 1438 (11th Cir. 1991)). "[W]ith respect to an issue on which the nonmoving party bears the burden of proof . . . the burden on the moving party may be discharged by 'showing' – that is, pointing out to the district court – that there is an absence of evidence to support the nonmoving party's case." Celotex, 477 U.S. at 325.

Once the moving party has satisfied its initial burden, the party opposing the motion must establish that a genuine issue as to a material fact exists. Jersey Cent. Power & Light Co. v. Lacey Township, 772 F.2d 1103, 1109 (3d Cir. 1985). The party opposing the motion for summary judgment cannot rest on mere allegations and instead must present actual evidence that creates a genuine issue as to a material fact for trial. Anderson, 477 U.S. at 248; Siegel Transfer, Inc. v. Carrier Express, Inc., 54 F.3d 1125, 1130-31 (3d Cir. 1995). "[U]nsupported allegations .

. . and pleadings are insufficient to repel summary judgment." Schoch v. First Fid. Bancorporation, 912 F.2d 654, 657 (3d Cir. 1990); see also FED. R. CIV. P. 56(e) (requiring nonmoving party to "set out specific facts showing a genuine issue for trial"). "A nonmoving party has created a genuine issue of material fact if it has provided sufficient evidence to allow a jury to find in its favor at trial." Gleason v. Norwest Mortg., Inc., 243 F.3d 130, 138 (3d Cir. 2001).

If the nonmoving party has failed "to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial, . . . there can be 'no genuine issue of material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." Katz v. Aetna Cas. & Sur. Co., 972 F.2d 53, 55 (3d Cir. 1992) (quoting Celotex, 477 U.S. at 322-23).

I. Plaintiff's motion for partial summary judgment regarding utility and enablement

Plaintiff moves for partial summary judgment on two of Watson's affirmative defenses to Ortho's claim for infringement of the '815 patent. Specifically, Plaintiff seeks judgment on Watson's affirmative defenses that claims 1 and 4 of the '815 patent are invalid for failure to satisfy the statutory utility and enablement requirements.

Watson begins its opposition by contending that the motion is "procedurally untenable because it seeks summary judgment on an issue, not a claim." (Def.'s Opp. Br. 1.) Watson – whose counsel submitted its opposition brief on October 25, 2010 – appears to be unaware (as Ortho has noted) that Rule 56(a) was amended effective December 1, 2010, and it now states: "A party may move for summary judgment, identifying each claim or defense – or the part of each

claim or defense – on which summary judgment is sought." All that is presently required is that the motion for summary judgment identify a part of a defense, which Ortho has done.

The utility requirement has its basis in the word "useful" in 35 U.S.C. § 101: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." The Federal Circuit discussed the utility requirement at length most recently in Janssen Pharmaceutica N.V. v. Teva Pharms. USA, Inc. (In re '318 Patent Infringement Litig.), 583 F.3d 1317, 1324 (Fed. Cir. 2009), which considered the application of the requirement in the context of pharmaceutical research. The Federal Circuit discussed utility relative to the ends of the continuum of empirical research into an invention. On the one hand:

> The utility requirement . . . prevents the patenting of a mere research proposal or an invention that is simply an object of research. . .[I]nventions do not meet the utility requirement if they are objects upon which scientific research could be performed with no assurance that anything useful will be discovered in the end.

Id. On the other hand, the required quantum of empirical evidence that a treatment method has utility is quite modest: "results from animal tests or in vitro experiments may be sufficient to satisfy the utility requirement." Id. at 1324-1325. Thus, there must be some evidence of the utility of a treatment method from research, but testing in humans is not required.

Turning to the patent at issue, the specification reviews a research study at length in Example 1, which begins: "There was conducted a randomized, multi-center study to evaluate three blinded regimens of norgestimate and ethinyl estradiol (NGM/EE) oral contraceptive and an open-label control regimen. One of these blinded regimens was a triphasic regimen

embodying the present invention." '815 patent col.10 ll.21 - 25. After a detailed description of the study method, the specification summarizes the results, which show that the occurrence of breakthrough bleeding when using the 25 microgram EE dosage regimen of the invention was "unexpectedly comparable to the incidence of breakthrough bleeding" for the prior art 35 microgram EE dosage regimen. Id. at col.12 ll.24 - 30.

The specification thus provides the results of a research study which showed that the invention was useful in that it unexpectedly produced an incidence of irregular bleeding comparable to a prior art regimen. This easily satisfies the utility requirement, as set forth in Janssen. The results of the research study show that the invention is useful for producing cycle control comparable to the prior art.

Watson has submitted an opposition brief that has pages of text, but it is difficult to discern in that text an argument on this issue that gives Defendant a leg to stand on. Much of Watson's argument is premised on the complaint that the specification contains no data showing the contraceptive efficacy of the invention. This relies on the faulty premise that there is a legal requirement that the specification demonstrate the invention's utility as an oral contraceptive. Watson has failed to persuade that existing law requires this. The statute, 35 U.S.C. § 101, and the relevant Federal Circuit case law, require that the invention be useful, and that there be evidence that the invented treatment method is useful, such that the invention is not a mere research proposal. The specification of the '815 patent sets forth the usefulness of the invented treatment method, and provides research which evidences that usefulness. This is sufficient to show that the invention is not a mere research proposal. Nothing in the law requires that contraceptive efficacy be shown.

To the contrary, in Janssen, the Federal Circuit relied on this holding from its predecessor Court in In re Krimmel, 292 F.2d 948, 953 (C.C.P.A. 1961):

> [W]e hold that when an applicant for a patent has alleged in his patent application that a new and unobvious chemical compound exhibits some useful pharmaceutical property and when this property has been established by statistically significant tests with standard experimental animals, sufficient statutory utility for the compounds has been presented.

Note that all the Krimmel Court required was that "*some* useful pharmaceutical property" be exhibited. The research study showing cycle control comparable to the prior art evidences a useful pharmaceutical property. It is clear from Janssen that, at least as to this holding, Krimmel is still good law. Janssen, 583 F.3d at 1325.

Furthermore, Watson's position resembles the challenger's argument that the Krimmel Court rejected. In Krimmel, the challenger – like Watson now – urged the Court to require a showing of utility for the "ultimate purpose" of the method, treatment of human iritis. 292 F.2d at 953. The Court rejected this position, holding that merely "some" useful pharmaceutical property be exhibited. Id. The Court concluded:

> We now hold only that appellant has established that his compounds have statutory utility even though he has not proven that they have the ultimate utility - prevention, alleviation, or cure of a disease in the human body. In this instance, appellant has proven sufficient utility to satisfy the requirement of 35 U.S.C. 101.

Id. at 954. Watson here advances a similar "ultimate utility" argument which does not reflect the statutory utility requirement.

Watson also contends that material factual disputes preclude a grant of summary judgment. This Court finds no material factual disputes that would preclude the entry of judgment as a matter of law. As to Watson's affirmative defense of invalidity due to failure to

meet the statutory utility requirement, Watson has failed to defeat the motion, and Ortho's motion for partial summary judgment will be granted.

Ortho also moves for summary judgment as to Watson's affirmative defense of invalidity due to failure to meet the statutory enablement requirement:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same . . .

35 U.S.C. § 112. Watson bears the burden of proof of its affirmative defense at trial. In opposition to Ortho's motion, Watson argues only that "a patent that fails to meet the utility requirement is not enabled." (Def.'s Opp. Br. 8.) Because this Court has rejected Watson's utility argument, this argument fails as well. As to Watson's affirmative defense of invalidity due to failure to meet the statutory enablement requirement, Watson has failed to defeat Ortho's motion, and this motion for partial summary judgment will also be granted.

II. Defendants' motions for partial summary judgment regarding double patenting

Watson and Lupin move for summary judgment of invalidity of claims 1 and 4 of the '815 patent due to nonstatutory double patenting, in view of claims 7 and 9 of the '006 patent. The Federal Circuit has set forth the analysis for a nonstatutory double patenting challenge as follows:

> Generally, an obviousness-type double patenting analysis entails two steps. First, as a matter of law, a court construes the claim in the earlier patent and the claim in the later patent and determines the differences. Second, the court determines whether the differences in subject matter between the two claims render the claims patentably distinct. A later claim that is not patentably distinct from an earlier claim in a commonly owned patent is invalid for obvious-type double patenting. A later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim.

Eli Lilly & Co. v. Barr Labs., 251 F.3d 955, 968 (Fed. Cir. 2001) (citations omitted).

The principal difference between the treatment regimen claimed in claims 1 and 4 of the '815 patent and that claimed in claim 9 of the '006 patent is that the EE dosage is 35 micrograms in the '006 patent and 25 micrograms in the '815 patent. Claim 9 in the '006 patent depends on claim 1, which claims an EE range of 20 to 50 micrograms. Thus, claim 1 of the '006 patent states a genus of treatment methods, and claim 9 in the '006 patent and claims 1 and 4 in the '815 patent are species within that genus. Claim 7 in the '006 patent is a subgenus of claim 1.

Watson first argues that claims 1 and 4 of the '815 patent are anticipated by claims 7 and 9 of the '006 patent. As just stated, claims 1 and 4 of the '815 patent claim a 25 microgram dosage of EE, while claim 7 of the '006 patent claims the range of 20 to 50 micrograms of EE and claim 9 claims a 35 microgram dosage of EE. Thus, off the bat, it is clear that claim 9 of the '006 patent cannot anticipate either claims 1 or 4 of the '815 patent, as the dosages are distinctly different. The only question is whether the subgenus stated in claim 7 of the '006 patent anticipates the species stated in claims 1 and 4 of the '815 patent.

The parties do not dispute that the relevant legal test asks whether the prior art genus "spell[s] out a definite and limited class of compounds that enable[s] a person of ordinary skill in the art to at once envisage each member of this limited class." Eli Lilly & Co. v. Zenith Goldline Pharms., Inc., 471 F.3d 1369, 1376 (Fed. Cir. 2006). In opposition, Ortho points to the expert testimony of Dr. Darney that one of ordinary skill in the art, looking at claim 7 of the '006 patent, would not have immediately seen the regimen of the '815 patent. (Pl.'s 56.1 Stmt. ¶ 118; Darney Decl. ¶ 6, Gould Decl. Ex. MMM.) This evidence is sufficient to raise a material factual question as to whether the subgenus stated in claim 7 of the '006 patent anticipates the species

stated in claims 1 and 4 of the '815 patent, and Ortho has defeated Watson's motion for summary judgment on this point.

Watson next argues that claims 1 and 4 of the '815 patent are obvious over claims 7 and 9 of the '006 patent. Watson observes that, because the 25 microgram dose disclosed in claims 1 and 4 of the '815 patent falls within the 20 - 50 microgram range disclosed in claim 7 of the '006 patent, it is presumed obvious. Watson then quotes from Ormco Corp. v. Align Tech., Inc., 463 F.3d 1299, 1311 (Fed. Cir. 2006):

> Where a claimed range overlaps with a range disclosed in the prior art, there is a presumption of obviousness. The presumption can be rebutted if it can be shown that the prior art teaches away from the claimed range, or the claimed range produces new and unexpected results.

In response, Ortho points to evidence in support of both conditions (teaching away and unexpected results).[1] As to teaching away, Ortho points to the Supplemental Expert Report of Dr. Darney, which discusses in detail numerous pieces of prior art that taught away from the '815

[1] Watson relies considerably on the contention that Federal Circuit law excludes secondary considerations of nonobviousness from the inquiry. (Def.'s Opp. Br. 6, 17.) This is incorrect. Watson relies on a footnote in Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1378 n.1 (Fed. Cir. 2003), which states only that nonstatutory double patenting does not *require* examination of secondary considerations. This does not mean that such considerations are excluded, as the Federal Circuit has made clear:

> In general, the obviousness analysis applies to double patenting, except for three distinctions. First, statutory obviousness compares claimed subject matter to the prior art, while non-statutory double patenting compares claims in an earlier patent to claims in a later patent or application. Second, double patenting does not require inquiry into a motivation to modify the prior art. Finally, double patenting does not require inquiry into objective criteria suggesting non-obviousness.

P&G v. Teva Pharms. USA, Inc., 566 F.3d 989, 999 (Fed. Cir. 2009). Watson has offered no support for the proposition that secondary considerations must be excluded from the nonstatutory double patenting analysis.

regimen by teaching that a reduction in estrogen would lead to a decrease in cycle control. (Gould Decl. Ex. A ¶¶ 119-141.) Ortho also points to the section in the Darney Supplemental Expert Report that discusses in detail the prior art that taught away from the '815 regimen by teaching that a reduction in estrogen would lead to a decrease in contraceptive efficacy. (Gould Decl. Ex. A ¶¶ 142 - 161.) As to unexpected results, Ortho points to the Supplemental Expert Report of Dr. Darney, which discusses in detail the evidence to support the inference that the '815 regimen produced unexpected results. (Gould Decl. Ex. A ¶¶ 213 - 243.)

The ultimate factual determination of whether the prior art taught away from the '815 regimen, and of whether the '815 regimen produced unexpected results, will likely rest on a battle of the scientific experts at trial. At this juncture, as to the question of whether claims 1 and 4 of the '815 patent are obvious in view of claim 7 of the '006 patent, this Court is satisfied that Ortho has raised an issue of material fact sufficient to preclude the entry of judgment as a matter of law and to defeat Watson's motion for summary judgment.

Watson next argues that claims 1 and 4 of the '815 patent are obvious over claim 9 of the '006 patent on its own, and that the 25 microgram regimen of the '815 patent and the 35 microgram regimen of the '006 patent are not patentably distinct. The evidence pertaining to the secondary considerations just discussed, however, also serves to raise material factual disputes that preclude a grant of summary judgment on this issue. Given Ortho's evidence of teaching away and unexpected results, the question of whether a 25 microgram regimen is obvious in view of a 35 microgram regimen cannot be resolved as a matter of law.

Ortho has offered evidence from which a reasonable jury could conclude that neither of claims 1 and 4 of the '815 patent are anticipated by, or obvious in view of, claims 7 and 9 of the

'006 patent. Ortho has pointed to evidence sufficient to raise questions as to material facts which preclude entry of judgment as a matter of law on Watson's nonstatutory double patenting challenge to the validity of claims 1 and 4 of the '815 patent. Lupin has relied on Watson's briefing in making its motion for partial summary judgment, which will be denied for the same reasons.

CONCLUSION

For the reasons stated above, Plaintiff has shown that it is entitled to judgment as a matter of law as to Watson's affirmative defenses that claims 1 and 4 of the '815 patent are invalid for failure to satisfy the utility and enablement requirements. Ortho's motion for partial summary judgment is granted, and Judgment on Watson's affirmative defenses that claims 1 and 4 of the '815 patent are invalid for failure to satisfy the utility and enablement requirements will be entered in Plaintiff's favor. Defendants Watson and Lupin have failed to demonstrate that they are entitled to judgment as a matter of law as to their nonstatutory double patenting challenge to the validity of claims 1 and 4 of the '815 patent, and Defendants' motions for partial summary judgment are denied.

s/ Stanley R. Chesler
Stanley R. Chesler, U.S.D.J.

Dated: January 25, 2011